UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 13, 2002

MEMORANDUM

Subject: Efficacy Review for 9480-7 / Sani-Wipe
DP Barcode: D281397
Case No.: 065184

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Through: Emily Mitchell, Team Leader Emily Mitchell 4/24/02
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Applicant: PDI

Formulation From Label:

Active Ingredient(s)	% by wt
n–Alkyl dimethyl benzyl ammonium chloride	0.175
Isopropyl alcohol	5.4800
Inert Ingredient(s)	94.5025
Total	100.0000

I **BACKGROUND:** PDI has submitted a product efficacy study as FIFRA 6(a)2 data. The study was conducted by Mycoscience, Inc. This report includes data on two different formulations of the product. Apparently, the second set of data was derived from a confirmatory disinfectant study on a new (alternate) formulation of this product. The MRID Number is 455372-01.

II Use Directions

- Especially designed for use on hard, non-porous food contact surfaces where the control of cross contamination is of prime importance
- Antibacterial
- Antimicrobial
- Kills common household germs and bacteria
- Sanitizes hard, non-porous surfaces
- For use on food contact surfaces
- Kills 99.999% of *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), *Listeria monocytogenes* (ATCC 19115), *Shigella boydii* (ATCC 9207), on food contact surfaces.
- For use in food service in healthcare settings.

Pre-clean if surface is visibly soiled.

Cleaning and Sanitizing Procedure: Use wipe to sanitize surface. Wipe enough for treated surfaces to remain visibly wet for 5 minutes. If needed, use additional wipes to keep surface area wet for a full 5 minutes. Let air dry. No rinsing required.

III Agency Standards for Proposed Claims

Efficacy of sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data derived from the AOAC Germicidal and Detergent Sanitizers Method.

(i) Test requirements. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both E. coli and S. aureus are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.

(ii) Performance standard. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and percentage reduction over the

control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.

IV Comments on the Submitted Efficacy Studies

MRID Number 455372-01: "Sani-Wipe Preliminary Testing Using EPA 4/12/01 Draft Interim Protocol" by R. Arsenault. Mycoscience, Inc. Study Completion Date 10/30/01. Test Report #01-0369NPNY (Report #1).

This assay was a modification of the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, and the Germicidal Spray Products as Disinfectants Methods to conform with the Draft Interim EPA/AD Method Guidance #02: Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes. The study tested Sani-Wipe formulation Number 7227-BJW-IV-55-D, Lot Number L-1256-B, 9/13/01. The challenge organism was *Staphylococcus aureus* (ATCC 6538). To support claims for use as a "one-step" cleaner/ disinfectant, a 5% organic soil load was added to the bacterial culture. Each wipe was tested against 2' x 2' surfaces inoculated with the challenge organism. Each 2' x 2' surface was made of eight 6" x 12" sections. After wiping, each surface section was allowed to set for 30 seconds and was then transferred to a sterile bag containing 2,000 mL of AOAC neutralizing broth. Thirty seconds after wiping the last surface section, the wipe was transferred to a sterile jar containing 100 mL of neutralizing broth. The bags and jars were sealed and sonicated for a period of 10 minutes, followed by additional agitation for 60 seconds prior to plating. Surface and wipe extracts were assayed for surviving numbers of microorganisms using the membrane filtration technique. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar (TGEA) plates containing neutralizers and were incubated for a minimum of 48 ± 2 hours at 37°± 1°C. After the incubation period the plates were counted.

V Results:

Staphylococcus aureus (ATCC 6538) Inoculated Carriers Treated with Sani-Wipes for 30-Seconds. Formulation #7227-BJW-IV-55-D, Lot # L-1256-B.

	Volume Filtered	CFU/Plate	Total Surviving CFU	Percent Reduction
Tray	0.2 mL	3	3.7×10^4	See Below
	2.0 mL	37		
	20 mL	TNTC		
Wipes	0.1 mL	84	8.7×10^4	See Below
	1.0 mL	TNTC		
			Mean Percent Reduction	99.845%

Total CFU Recovered: 1.24×10^5
Control Surface Count: 8.0×10^7

TNTC = Too Numerous To Count

Staphylococcus aureus (ATCC 6538) Inoculated Carriers Treated with Sani-Wipes for 30-Seconds. Formulation #7227-BJW-IV-55-C, Lot # L-1256-A.

	Volume Filtered	CFU/Plate	Total Surviving CFU	Percent Reduction
Tray	0.2 mL	3	1.3×10^4	See Below
	2.0 mL	13		
	20 mL	---		
Wipes	0.1 mL	5	5.0×10^3	See Below
	1.0 mL	50		
			Mean Percent Reduction	99.999%

Total CFU Recovered: 1.24×10^5
Control Surface Count: 8.0×10^7

VI Conclusions

MRID Number 455372-01: When tested by wiping one towelette against 2' x 2' surfaces inoculated with *Staphylococcus aureus* (ATCC 6538) and allowing a 30 second exposure, Sani-Wipes Formulation #7227-BJW-IV-55-C, Lot # L-1256-A achieved a bacterial reduction of 99.999%.

Sani-Wipes Formulation #7227-BJW-IV-55-D, Lot # L-1256-B, **failed** to achieve a bacterial reduction of 99.999%. These results only pertain to Formulation D of this product.